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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,639	09/22/2006	Karsten Wassermann	DRF 3.3-054	2889

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EXAMINER	
WEBB, WALTER E	

ART UNIT	PAPER NUMBER
1609	

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10/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,639	WASSERMANN ET AL.	
	Examiner	Art Unit	
	Walter E. Webb	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/12/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-46 are pending and rejected.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 30-42 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

For the purposes of examination claims 30-42 will be treated as product claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30-42 provide for the use of balaglitazone and one or more other anti-diabetic compounds, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

For the purposes of examination claims 30-42 will be treated as product claims.

Furthermore, claims 2, 16, 18, 32, 45, are improper Markush groups. Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 14-18, 29-31 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Andersen et al., (WO 01/19831; published March 22, 2001).

Applicant claims a pharmaceutical comprising balaglitazone and one or more other anti-diabetic compounds (claim 1, 14, 30 and 31). Applicant also claims a method for treating conditions from a decrease in insulin resistance (claims 15, 16 and 18), and a method delaying the progression of non-insulin requiring Type II diabetes to insulin requiring Type II diabetes (claims 17, 29 and 46).

Andersen et al. teach a protein tyrosine phosphatase inhibitor (an anti-diabetic compound) in combination with balaglitazone, where balaglitazone is represented by 5-[[4-[3-Methyl-4-oxo-3,4-dihydor-2-quinazolinyl]methoxy]phenyl-methyl]thiazolidine-2,4-dione or a pharmaceutically acceptable salt thereof. (See pg. 139, claim 91, lines 20-28; see also pg. 42, lines 9-13.) They teach that their tyrosine phosphatase inhibitor in combination with balaglitazone would be useful in the treatment of obesity and Type II diabetes, as per clams 15, 17, 29 and 46. (See pg. 6, lines 19-22, and 32-35; see also pg. 40, lines 18-22.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen et al., (*supra*), in view of Bussolari et al., (US 2003/0055091).

Applicant's invention is drawn to a composition and a method for treating obesity and Type II diabetes. The composition for treating these diseases includes balaglitazone and one or more anti-diabetic compounds, where the anti-diabetic compounds can be insulin, insulin secretagogues, insulin sensitizers, biquanides, alpha-glucosidase inhibitors, glucagons antagonists, protein tyrosine phosphatase inhibitors, RXR agonists, glucose uptake modulators, and lipid lowering compounds (claims 2-13, 16-28, 32-42 and 45). The composition is presented in a single container or separate containers (claims 13, 14, 43 and 44).

Andersen teaches a combination of a protein tyrosine phosphatase inhibitor with one or more insulin sensitizer, such as a troglitazone, ciglitazone, pioglitazone, rosiglitazone, or balaglitazone (5-[[4-[3-Methyl-4-oxo-3,4-dihydor-2-quinazolinyl]methoxy]phenyl-methyl]thiazolidine-2,4-dione). (See claim 91 at pg. 139, lines 20-28.) In a preferred embodiment the protein tyrosine phosphatase inhibitor is administered in combination with one or more of a compound such as balaglitazone in combination with insulin and lovastatin, for example. (See pg. 42, lines 28-31) Other compounds that can be combined with the protein tyrosine phosphatase inhibitors include one or more of balaglitazone, insulin, meglitinides, gliclazide, glimepiride, glipizid, nateglinide, troglitazone, ciglitazone, pioglitazone, rosiglitazone, isaglitazone, metformin, miglitol, acarbose, PPAR agonist, lovastatin, simvastatin, and gemfibrozil.

(See pg. 41, lines 23-33; see also pg. 42, lines 3-6, line 8, line 10, line 19, and lines 23-27.)

Andersen does not explicitly teach combining balaglitazone with one or more of the above compounds or that the insulin can be, for example, B28Lys-B29Pro human insulin.

Bussolari et al. teach a combination therapy comprising RXR modulators and glucose reabsorption inhibitors useful for the treatment of diabetes (IDDM, NIDDM), and obesity. (See pg. 1, paragraphs [0012] and [0016]. They also teach that the composition can include insulins such as 28B-L-Lys-29B-Pro human insulin. (See pg. 12, paragraphs [0238]-[0244].)

It would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to combine the balaglitazone and one or more other anti-diabetic compounds of Andersen, as claimed, for treating obesity and type 2 diabetes since Andersen teach that protein tyrosine phosphatase inhibitor (an anti-diabetic compound) can be combined with balaglitazone and one or more compounds, where the other compounds of Andersen are claimed in the instant application. It also would have been obvious to the artisan to include insulins such as B28Lys-B29Pro human insulin as a type of insulin, generically disclosed in Andersen, combined with balaglitazone since Bussolari teach insulins such as B28Lys-B29Pro human insulin in combination with other anti-diabetic compounds for the treatment of type 2 diabetes and obesity.

Because Andersen teaches combination therapy for treating type 2 diabetes and obesity, which include balaglitazone and another anti-diabetic compound, where the

other anti-diabetic compound include those claimed in the instant application, the artisan would reasonably predict success in treating type 2 diabetes and obesity by combining balaglitazone with another anti-diabetic compound given the options for combination therapy taught by Andersen. "[A] person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1390.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 9:00am-5:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

WW

JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER